510 (k) Summary

A. Submitter Information:

Submitter's Name:	PROMEPLA SAM
Address:	9 Avenue Prince Albert II "LE COPORI" MC 98000 MONACO (Principality of)
Contact Person:	David Tripodi
Contact Person's Number:	(377) 97984233
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Date of Preparation:	January 14, 2012

B. Device Name:

Trade Name:	ROCAMED RocaUS Platinum
Common Name:	Ureteral Access Sheath
Classification Name(s):	Accessories, Catheter, G-U
Produce Code:	KNY
CFR Reference:	21 CFR 876.5130

C. Predicate Device Name:

Trade Names:	AMCI UroPass Ureteral Access Sheath (K051593) Boston Scientific Navigator Access Sheath Set II (K030956)

D. Device Description:

The ROCAMED RocaUS Platinum is designed to create a conduit for urological procedural instruments. The device consists of two components: a flexible, coil reinforced sheath and a semi-rigid dual lumen dilator catheter with tapered distal tip. Both components are radiopaque and have hydrophilic coating. This device is sold in two sizes, 10/12 and 12/14 FR.

E. Intended Use:

The ROCAMED RocaUS Platinum is intended to be a conduit for passage of endoscopes and other urological devices for the purpose of performing ureteroscopy procedures. The dual working lumen dilator with luer lock connections allows the user to insert guidewires and fluids.

F. Technological Characteristics Summary:

The ROCAMED RocaUS Platinum is flexible coil reinforced sheath with hydrophilic coating. The device can be inserted by placing the dilator/sheath assembly over a guidewire, inserting it into the patient and unclipping the dilator from the sheath and removing the dilator, leaving the sheath in place. The sheath allows for safe passage of endoscopes, injection or aspiration of fluids and other related instruments.

Table 1 provides a comparison summary of the technological characteristics of the ROCAMED RocaUS Platinum versus the predicate devices.

Table 1

Summary of Equivalence of the ROCAMED RocaUS Platinum to Predicate Devices

	Proposed Device	Predicate Device	Predicate Device
Product Name **510(k) Number**	ROCAMED RocaUS Platinum	AMCI UroPass Ureteral Access Sheath K051593	BSCI Navigator Access Sheath Set II K030956
Product Code, Regulation #, Name	KNY 21 CFR 876.5130, Urological catheter and accessories.	KNY 21 CFR 876.5130, Urological catheter and accessories.	KOG 21 CFR 876.1500, Endoscope and Accessories GBM 21 CFR 876.5130, Urological catheter and accessories.
Manufacturer	Promepla SAM	Gyrus ACMI	Boston Scientific
Intended Use	The ROCAMED RocaUS Platinum is intended to be a conduit for passage of endoscopes and other urological devices for the purpose of performing ureteroscopy procedures. The dual working lumen dilator with luer lock connections allows the user to insert guidewires and fluids.	The UroPass Ureteral Access Sheath is intended to be a conduit for the passage of endoscopes and other urological devices for the purpose of performing diagnostic and surgical procedures such as nephrostomy, cystoscopy, or ureteroscopy, in the urinary tract.	The UASS II is indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract antegrade and/or retrograde access.
Reuse Status	Disposable. For single patient use only	Disposable. For single patient use only	Disposable. For single patient use only
Sterile	Yes	Yes	Yes
Lumen	2	1	1
Dilator Material	LDPE+$BaSO_4$	PTFE+ $BaSO_4$	PTFE+ $BaSO_4$
Sheath Material	Pebax-SST-PTFE	SST-PTFE	SST-PTFE
X-Ray Opaque	Yes	Yes	Yes
Coil Reinforced	Yes	Yes	Yes
Fr Size	10/12,12/14	12/14	11/13, 13/15

Length	35 cm	24, 38, 54 cm	28, 36, 46 cm
Guide wire Compatibility	0.032", 0.035"	Yes	0.035", 0.038"
Atraumatic Tip	Yes	Yes	Yes
Tapered Dilator	Yes	Yes	Yes
Radiopaque Marks	Yes	Yes	Yes
Hydrophilic Coating	Yes	Yes	Yes
Injection of Contrast Media	Yes	Yes	Yes
Proximal End Funnel	Yes	Yes	Yes

Dilator material is different from the predicate devices, LDPE instead of PTFE. It was selected instead of PTFE because it is slightly more flexible, which will ease insertion into the patient and reduce trauma.

G. Performance Data:

Results of physical and functional testing support a determination of substantial equivalents for the ROCAMED RocaUS Platinum when compared to the predicate devices. The ROCAMED RocaUS Platinum is substantially equivalent to devices currently market approved in terms of intended use, technology, principles of operation and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Krista Johnson
Quality Group - Regulatory Affairs
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MONACO

MAY 14 2012

Re: K120160
Trade/Device Name: ROCAMED RocaUS Platinum
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KNY, KOD
Dated: May 4, 2012
Received: May 7, 2012

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement (K98-1)

510(k) Number (if known): K120160

Device Name: ROCAMED RocaUS Platinum

Indication for use:

The ROCAMED RocaUS Platinum is intended to be a conduit for passage of endoscopes and other urological devices for the purpose of performing ureteroscopy procedures. The dual working lumen dilator with luer lock connections allows the user to insert guidewires and fluids.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE 6 CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Gayle Bunn for Benjamin Fisher

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120160